Requests to make oral comments should contain the name, address, telephone number, and organizational affiliation of the presenter. Depending on the time available and the number of requests to make oral comments, it may be necessary to limit the time of each presenter.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Anne Wilson, Program Analyst, Office of the Director, NCEH, CDC, 4770 Buford Highway, NE, M/S F49, Atlanta, Georgia 30341–3724, telephone 770/488–7321, e-mail amw6@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 30, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–29601 Filed 11–4–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Antiviral Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 1, 1998, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Rhonda W. Stover or Sandra L. Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committees will jointly discuss new drug application (NDA) N20–629, to switch penciclovir (Denavir®, SmithKline Beecham) topical cream from prescription status to over-the-counter status for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 24, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 24, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 27, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–29561 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0298]

Guidance for Industry on General/ Specific Intended Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Industry on General/ Specific Intended Use.'' FDA developed this guidance to satisfy a new section of the Federal Food, Drug, and Cosmetic Act (the act), which was added by the Food and Drug Administration Modernization Act of 1997 (FDAMA). This new section directs the agency to issue guidance explaining the general principles used by FDA in determining when a specific use may be added to a legally marketed device using premarket notification (510(k)) procedures and when a specific use triggers the need for a premarket approval (PMA) application.

DATES: Written comments concerning this guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your electronic or written request, or fax your request to 301–443–8818. Submit written comments on ''Guidance for Industry on General/Specific Intended Use'' to the contact person. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance entitled ''Guidance for Industry on General/Specific Intended Use.''

FOR FURTHER INFORMATION CONTACT: Daniel G. Schultz, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–5072.

SUPPLEMENTARY INFORMATION:

I. Background

Congress indicated that FDA should provide additional guidance on the approach that the agency takes when evaluating whether a new use, which appears to fall within the scope of the intended use of a legally marketed predicate device, is a new intended use that would require a PMA. This guidance is issued in accordance with the new section 513(i)(1)(F) of the act (21 U.S.C. 360c(i)(1)(f)), which was added by section 206 of FDAMA. The purpose of this document is to help medical device manufacturers understand the principles used by FDA to determine whether the addition of a specific indication for use to a medical device cleared for marketing with a general indication for use could trigger the need for a PMA application. The guidance is intended to help manufacturers answer the following questions: Under what circumstances is the device with a new, specific indication for use likely to be found to be substantially equivalent to a device legally marketed for a general indications for use? Conversely, when does a specific indication for use become a new intended use that requires submission of a PMA to establish the safety and effectiveness of the device? FDA announced the